REMARKS

Claims 71-87 are pending in the application. Applicants respond to the issues raised in the Office Action mailed March 6, 2006 as follows.

Priority

The Office Action asserts that "provisional application 60/144703 (7/20/1999), relied on by the parent patent # 6673108 offers no support for an in-growth matrix comprising a concentration gradient of material and therefore priority is not granted to this date. The earliest priority date granted to this application is 11/5/1999 as per the filing date of US Pat# 6554857." Applicants respectfully disagree with this assertion and note that it is not relevant with respect to the art cited by the Examiner against the pending claims.

Double Patenting

Claims 71-83 and 85-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,673,108. Applicants disagree with the Examiner's position regarding double patenting, but in the interest of expediting prosecution of this application, Applicants file concurrently with this Response a Terminal Disclaimer, disclaiming the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of U.S. Patent No. 6,673,108. Applicants assert that the filing of the Terminal Disclaimer obviates the double patenting rejection and respectfully request that the rejection be withdrawn.

35 USC 102

Claims 71-84 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,993,072 issued to Zaffaroni ("Zaffaroni"). Applicants respectfully traverse this rejection.

As an initial matter, Applicants note that the assertion that Zaffaroni discloses "continuous and non-continuous pores that may be connected" is not supported in the part of the specification cited in the Office Action, i.e., col. 10, lines 40-55, which is reproduced as follows:

> The pore structure further includes continuous pores, which pore is one that has an opening on both faces of the microporous wall connected therethrough. For example, substantially cylindrical channels or cavities of various regular or irregular shapes including conventional forms such as uniform straight, uniform curved-linear, uniform curved, dispersed straight continuous pores, randomly oriented continuous pores, hindered connected through pores, and the like pores that defined a diffusional path for passage through the microporous wall.

As is evident from this paragraph, the "continuous" pores of Zaffaroni are individual channels

connecting one side of a walled structure to the other side of the wall. If the Examiner is relying on the phrase "hindered connected through pores" as support for a disclosure of "interconnecting" pores in the claimed invention, Applicants note that this phrase is at a minimum ambiguous if not nonsensical to one of skill in the art. Moreover, all of the Figures in Zaffaroni clearly show "micropores 15" as being individual and separate channels disposed in the wall 11 of device 10. None of the "micropores 15" are connected to any other "micropore 15." Because the claims of the present application specifically recite "interconnected, uniformly shaped pores," for at least this reason, the rejection over Zaffaroni cannot be maintained.

Moreover, the drug delivery device of Zaffaroni is described in the Abstract as follows:

> A drug delivery device for administering a drug at a controlled rate for a prolonged period of time ... is comprised of a wall surrounding a reservoir containing a drug. The reservoir is formed of a solid drug carrier permeable to the passage of the drug. The wall is formed in at least a part of a microporous material the pores of which contain a drug release rate controlling medium also permeable to the passage of the drug, but the rate of passage of the drug through the medium is lower than the rate passage of the drug through the solid drug carrier so that drug release by the medium in the microporous wall is the drug release rate controlling step for releasing drug from the drug delivery device.

Thus, if Zaffaroni creates a gradient at all, it is created by virtue of two materials having differing permeabilities with respect to a drug. Thus, in Figure 1 of Zaffaroni, any gradient exists only at the interface of layers 11 and 13 based on the differing drug permeabilities of the solid drug carrier 13 (also called the reservoir and described at col. 13, line 55 - col. 14, line 12) and the drug release rate controlling medium (not specifically identified in Figure 1 but which is contained in the micropores 15 of wall 11 surrounding drug 14 and described at col. 11, lines 53-64 and col. 12, lines 23-37). See col. 4, lines 45-55. In contrast, above and beyond the fact that independent claim 71 does not recite "drug," the present invention requires that the concentration gradient be a part of the ingrowth matrix itself, and since that ingrowth matrix is located "within the pores" of the claimed prosthetic material, the concentration gradient exists within the pores, and not just at an interface between two layers having different drug permeabilities, e.g., as with the interface between layers 13 and 11 in Figure 1 of Zaffaroni. Because the claims specifically recite "an ingrowth matrix within the pores, wherein the ingrowth matrix comprises a concentration gradient," for at least this reason, the rejection over Zaffaroni cannot be maintained.

Claims 71, 72, and 85-87 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,718,907 issued to Karwoski et al. ("Karwoski et al."). Applicants respectfully traverse this rejection.

The Office Action states that "Karwoski discloses a scaffold with uniformly shaped pores (Figure 1) which is an in-growth matrix comprising a concentration gradient of fluorine to carbon (col. 2, lines 15-50)." The specification of Karwoski et al. describes what is shown in Figure 1 as "an interwoven fabric tube substrate" (col. 3, ll. 67-68) and wherein "the tube comprises a multiplicity of circumferentially-oriented, fill threads 12 interwoven in a one-over-one relationship with longitudinally oriented non-elastic warp threads 14" (col. 5, ll. 46-50). It is unclear from this quotation and from Figure 1 what the Examiner considers to be the "pore" as recited in independent claim 71, i.e., the unlabeled spaces between the threads 12 and 14 in Figure 1 or the general statement in the specification that the substrate may have a "porous" surface (col. 3, l. 42). In either case, however, there is no disclosure that the alleged "pores" are "interconnected," which is admitted in the Office Action sub silencio in not asserting that Karwoski et al. discloses "interconnected" pores and only asserts that Karwoski et al. discloses "uniformly shaped pores." If the "pores" are the unlabeled spaces between the threads 12 and 14 in Figure 1, it is visually clear that the "pores" are separated from one another by the threads 12 and 14. If the "pores" are the general reference to a "porous" substrate, nowhere in the specification of Karwoski et al. is there a disclosure that those "pores" are interconnected (and for that matter, no disclosure that the pores are uniform as recited in the claims). Because the claims specifically recite "interconnected, uniformly shaped pores," for at least this reason, the rejection over Karwoski et al. cannot be maintained.

Moreover, the Office Action states that "Karwoski discloses a scaffold with uniformly shaped pores (Figure 1) which is an in-growth matrix comprising a concentration gradient of fluorine to carbon (col. 2, lines 15-50)." Karwoski et al. describe coating a tubular woven substrate using a fluorinated gas (col. 7, l. 50 et seq.) to produce external and internal coatings with particular fluorine/carbon ratios. In particular, Karwoski et al. disclose a tubular vascular graft having an inside surface C/F ratio greater than 1.5 and an outside surface C/F ratio of 0.5 (see, e.g., col. 9, lines 28-32). As an initial matter, it appears from the language in the Office Action that the woven substrate of Karwoski et al. is considered to be both the claimed scaffold and the claimed in-growth matrix. However, it is clear from Applicants' specification that the claimed scaffold and the claimed in-growth matrix are different features and that the in-growth matrix is present throughout the pores of the scaffold (see, e.g., Figure 4 and page 9, lines 1-13). Thus, the present invention requires that the concentration gradient be a part of the ingrowth matrix itself, not the scaffold. Because the claims specifically recite "an ingrowth matrix within the pores, wherein the ingrowth matrix comprises a concentration gradient," for at least this reason, the rejection over Karwoski et al. cannot be maintained.

Conclusion

In view of the arguments above and the filing of the Terminal Disclaimer, Applicants assert that all of the rejections have been overcome and respectfully request that all of the rejections of the claims be withdrawn and that claims 71-87 be allowed to issue.

The Examiner is encouraged to contact the attorney listed below if there are any further questions regarding this application.

Respectfully submitted for,

Zilla, et al.

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